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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,006	09/20/2001	Charles Young	07039-346001	2450

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/957,006	YOUNG ET AL.	
	Examiner	Art Unit	
	Randall Winston	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *3-11 and 20-40* is/are pending in the application.

4a) Of the above claim(s) *20-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 02/13/2004.

Claims 3-11 are under examination.

Newly submitted claims 20-40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally presented claims (claims 3-11) were examined over the art insofar as the read upon a method of treating an individual with prostate cancer (i.e. BPH) or at risk of developing prostate cancer or reducing the risk of recurrence of prostate cancer comprising the steps of administering a dose of POH or a derivative thereof to said individual effective to inhibit the transactivating ability of an androgen receptor, and monitoring the transactivating ability of said androgen receptor in said individual, wherein inhibiting the transactivating ability of said androgen receptor inhibits the proliferation of prostate cancer cells, thereby reducing the risk of recurrence of prostate cancer in said individual. However, newly presented claims 20-40 are drawn to a method of treating an individual with prostate cancer (i.e. BPH) or at risk of developing prostate cancer or reducing the risk of recurrence of prostate cancer comprising the steps of administering a dose of POH or a derivative thereof to said individual effective to inhibit the transactivating ability of an androgen receptor, and monitoring said individual for a dose-dependent reduction in prostate-specific antigen (PSA) levels and/or monitoring human glandular kallikrein (hK2) levels in said individual, wherein said dose-dependent reduction in PSA correlates with a dose-dependent inhibition of

said transactivating ability of said androgen receptor and/or wherein a reduction in hK2 correlates with an inhibition of said transactivating ability of said androgen receptor. They are different inventions because the original presented claims and the newly presented claims are unrelated methods because the inventive groups are directed to different inventions which are not connected in design, operation, and/or effect. The original presented claims monitors the transactivating ability of said androgen receptor in said individual whereas the newly presented claims monitors said individual for a dose-dependent reduction in prostate-specific antigen (PSA) levels and/or monitoring human glandular kallikrein (hK2) levels in said individual. Accordingly, claims 20-40 are withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-11 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 7 and 10 recite the terms "derivative of." No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning "derivative thereof ." There is no definition of "derivative thereof" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the

claimed invention. Applicant has not overcome this rejection by clearly delineating the metes and bonds of what is "derivative thereof."

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7 and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Imagawa et al. (US 6133324).

Applicant argues that applicant's independent claims 7 and 10 recite 'administering a dose of perilly alcohol (POH) or a derivative thereof to said individual effective to inhibit the transactivating ablility of an androgen receptor.... The cited reference does not teach or suggest that POH or a derivative thereof can act to inhibit the transactivating ablility of the androgen receptor. Applicant argument is not found persuasive because as examiner explained in his non-final office action of 09/09/2003, that the underlying functional effects instantly claimed (i.e. inhibiting the tranactivating ability of an androgen receptor) would be intrinsic upon administration of an anti-cancer effective amount of perillyl alcohol to such a patient.

Claims 3-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Imagawa et al. (US 6133324) in view of Shyjan et al. (US 6355430).

Applicant argues that Imagawa et al. reference does not disclose that the anti-cancer activity of POH is due to inhibiting the transactivating ability of the androgen receptor. The Shayhan et al. reference does not teach that POH or a derivative thereof is anti-androgen agent. The Examiner has used improper hindsight by combining a reference that discloses the anti-cancer activity of POH (Imagawa et al.) with a reference that examines the transactivating ability of the androgen receptor (Shyhan et al.). Applicant argument is not found persuasive because as examiner explained in his non-final office action of 09/09/2003, it would have been obvious to one of ordinary skill in the art at the time the claimed invention to modify the teachings taught by Imagawa et al.'s with respects to the proven anti-cancer activity perilly alcohol provides when administered *in vivo* to an individual to include the beneficial teachings taught by Shyjan et al.of administering an anti-androgen agent to cultured prostate cells to serve as a marker for monitoring the transactivating ability of an androgen receptor for the treatment of prostate cancer in an individual whereas both combined teaching would obtained an improved claimed invention method of treating prostate cancer and/or prostate precancerous conditions (i.e BPH) in an individual. Furthermore, one of ordinary skill in the art would have been motivated to include the adjustment of other conventional working conditions such as (e.g. the effective dose of perilly alcohol and how perilly alcohol is administered), because these conventional working conditions are

deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Moreover, the art-recognizes functional or mechanical equivalency of a claimed compound/element with that of the prior art compound/element provides a *prima facie* case of obviousness for the skilled artisan to interchangeably substitute one equivalent for the other (see, e.g. MPEP 2144.06) within a preparation (i.e. the substitution of anti-androgen agents to monitor the transactivating ability of an androgen receptor for the treatment of prostate cancer).

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600